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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/674,701 | 09/30/2003 | Roger Petrus Gerebern Vandecruys | JANS-0063 | 4563 |

45511 7590 05/28/2008

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| EXAMINER | |
|---|---|
| YOUNG, MICAH PAUL | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 05/28/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/674,701 | VANDECRUYS ET AL. | |
| | Examiner | Art Unit | |
| | MICAH-PAUL YOUNG | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-28,32,33,36,37 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28,32,33,36,37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 1/23/08.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 20-28, 32, 33, 36, 37 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Rickey et al (USPN 5,792,477 hereafter '477) in view of Shimizu et al (USPN 5,824,339 hereafter '339) and Curatolo et al (USPN 5,605,889 hereafter '889). The claims are drawn to a solid formulation comprising 9-hydroxy risperidone, or a pharmaceutically acceptable salt, and one or more hydrophilic polymers.

2. The '477 patent teaches a microparticle formulation comprising biodegradable polymers such as poly-lactic acids and 9-hydroxy risperidone, along with other hydrophilic polymers such as polyvinyl pyrrolidone, and carboxymethylcellulose (col. 5, lin. 29-56; col. 13, lin. 60-col. 14, lin. 11). The hydrophilic polymers are present in an amount from 0.5-2% wt. (*Ibid.*). The reference discloses a method for the delivery of the microparticles to a patient (col. 7, lin. 35-43). The reference is silent to the inclusion of pregelatinized starch yet the inclusion of such a common excipient is well known it the art as seen in the '339 patent.

3. The '339 reference discloses antibiotics in combination with various water-soluble polymers (col. 5, lin. 9-35). The hydrophilic polymers include hydroxypropylcellulose with a viscosity between 1-150,000 cps (col. 4, lin. 55-60), and hydroxypropylmethylcellulose with a viscosity between 1-40,000 centistokes (col. 5, lin. 1-8). The formulation can comprise both celluloses at prescribed ratios (col. 6, lin. 52 – 62), in addition to further excipients such as pregelatinized starches and other well-known excipients (col. 6, lin. 42). One of ordinary skill in the art would have been motivated to include the viscous hydroxypropyl cellulose polymers of the '339 reference in order to improve the stability of the microparticle formulation. Further since both references comprise similar components such as carboxymethylcellulose and other hydrophilic polymers, an artisan of ordinary skill would be able to simply substitute the viscous polymers in order to improve the stability. The reference is silent however to the specific concentration of pregelatinized starch present in the formulation. These concentrations can be found in the '889 patent.

4. The '889 patent discloses an oral tablet formulation comprising hydrophilic components admixed together with pregelatinized starch (abstract). The pregelatinized starch is present in an amount of approximately 5.8% by weight (col. 6, lin. 28-54). The reference establishes the level of skill in the art regarding the inclusion of pregelatinized starch into a tablet formulation. It establishes the pregelatinized starch should be added to a solid oral tablet formulation is concentration of about 5 %, and that these formulations are well known to also include one or more hydrophilic polymers (col. 6, lin. 62-68).

5. Regarding the media of changing ionic strength, it is the position of the Examiner that such a limitation is irrelevant to the structure of the tablet formulation and holds no patentable

weight. The structure of the tablet is identical to the combination in the prior art. Further since the fluid is within the gastrointestinal tract, it merely means that the tablet is taken orally, which the combination of the prior art is. For these reasons the limitations are given no patentable weight.

6. With these things in mind it would have been obvious to combine the highly viscous polymers of the '339 patent with the formulation of the '477 patent in order to provide stability and a controlled release to the microparticles. It would have been obvious to follow the suggestions of the '339 patent to include pregelatinized starch to include the compound in specific concentrations as seen in the '889 patent. The '447 suggests the inclusion of carboxymethylcellulose, while the '339 patent discloses the use of either carboxymethylcellulose or hydroxypropylcellulose polymers. It would have been obvious to combine the teachings with an expected result of a control releasing formulation of a solid dosage from.

***Response to Arguments***

Applicant's arguments with respect to claims 20-28, 32, 33, 36, 37 and 39 have been considered but are moot in view of the new ground(s) of rejection. However it remains the position of the Examiner that The Shimizu and Rickey patents continue to provide obviating disclosures. First the '477 patent discloses an oral solid tablet comprising the active agents and polymers of the instant claims. The reference is silent to the viscosities of the hydrophilic polymers but these polymers are discloses in the '339 patent which further discloses the inclusion of commonly known components such as pregelatinized starch. The concentration so pregelatinized starch is well known in the art as seen in the '889 patent. For these reasons the claims remain obviated.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618